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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,729	09/12/2003	Diana R. McWilliams	122294-1007	8275

7590 09/15/2004  
Carol M. Nielsen  
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EXAMINER
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LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/661,729

Applicant(s)

MCWILLIAMS ET AL.

Examiner

Frank W Lu

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-7 and 18-24, drawn to a method of analyzing genetic expression (claims 1-7) and a method for extraction and isolation of genetic molecules (claims 18-24), classified in class 435, subclass 6.
  - II. Claims 8, 27, 28, and 38, drawn to a first apparatus, classified in class 422, subclass 68.
  - III. Claims 9-15 and 29-35, drawn to a method of analyzing genetic expression (claims 9-15) and a method for extraction and isolation of genetic molecules (claims 29-35), classified in class 435, subclass 6.
  - IV. Claims 16, 17, and 39, drawn to a second apparatus, classified in class 422, subclass 68.
  - V. Claims 25, 26, 36, and 37, drawn to a method of extracting genetic molecules from an animal (claims 25 and 36) and a method of isolating RNA from an animal (claims 26 and 37), classified in class 435, subclass 6.
2. The inventions are distinct, each from the other because of the following reasons:

Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

Art Unit: 1634

§ 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product such as nucleic acid or protein purification.

Groups I and III are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group I such as the liquefying step of claim 1 is not required for Group III while the search required for Group III such as the pulverizing step of claim 9 is not required for Group I.

Groups I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product such as nucleic acid or protein purification.

Groups I and V are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group I such as the microarray of claim 1 is not required for Group V while the search required for Group V such as the freezing step of claim 25 is not required for Group I.

Groups II and III are distinct and independent inventions in that they are directed to a product and a method. As a result, different and distinct searches will have to be performed. For example, the search required for Group II such as the apparatus is not required for Group III

Art Unit: 1634

while the search required for Group III such as the pulverizing step of claim 9 is not required for Group II.

Groups II and IV are distinct and independent inventions in that they are directed to two different products. As a result, different and distinct searches will have to be performed. For example, the search required for Group II such as the component that liquefies the complex biological construct is not required for Group IV while the search required for Group IV such as the component that pulverizes the complex biological construct is not required for Group II.

Groups II and V are distinct and independent inventions in that they are directed to a product and a method. As a result, different and distinct searches will have to be performed. For example, the search required for Group II such as the apparatus is not required for Group V while the search required for Group V such as the freezing step of claim 25 is not required for Group II.

Groups III and IV are distinct and independent inventions in that they are directed to a product and a method. As a result, different and distinct searches will have to be performed. For example, the search required for Group III such as the pulverizing step of claim 9 is not required for Group IV while the search required for Group IV such as an apparatus is not required for Group III.

Groups III and V are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group III such as the microarray of claim 9 is not required for Group V while the search required for Group V such as the freezing step of claim 25 is not required for Group III.

Art Unit: 1634

Groups IV and V are distinct and independent inventions in that they are directed to a product and a method. As a result, different and distinct searches will have to be performed. For example, the search required for Group IV such as an apparatus is not required for Group V while the search required for Group V such as the freezing step of claim 25 is not required for Group IV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. A telephone call was made to Ms. Carol Nielsen (Reg. No. 37,676) on September 2, 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30.

Art Unit: 1634

(November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703)872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746.

The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu  
PSA  
September 13, 2004



**FRANK LU**  
**PATENT EXAMINER**